UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,894	12/31/2003	Charles S. Neer	L-F/231/273	8901

7590 04/30/2009

WOOD, HERRON & EVANS, L.L.P.
2700 Carew Tower
441 Vine St.
Cincinnati, OH 45202

EXAMINER	
DOUKAS, MARIA E	
ART UNIT	PAPER NUMBER
3767	
MAIL DATE	DELIVERY MODE
04/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,894	NEER, CHARLES S.	
	Examiner	Art Unit	
	MARIA E. DOUKAS	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-43* is/are pending in the application.

4a) Of the above claim(s) *41-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 21-40, in the reply filed on 2/2/2009 is acknowledged.

2. Claims 41-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/2/2009.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 32 and 35-40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

According to MPEP §2106 and (*In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Fed. Cir. 2008)), a method claim must meet a specialized, limited meaning to qualify as a patent-eligible process claim. The test for a method claim is whether the claimed method is (1) tied to a particular machine or apparatus, or (2) transforms a particular article to a different state or thing. In the case of claims 32 and 35-40, the claimed steps in the method are not tied to any machine or apparatus. Claim 32 recites providing a data collection routine, receiving input from the user, and updating a syringe

definition, however, these steps are not tied to a specific machine or apparatus as required to be statutory subject matter. Further, claims 35-40 go to further defining the steps of claim 32 and do not add any machine or apparatus to tie the steps.

Independent claims 21 and 27 are not rejected under 101, because although they too are method claims for operating a motorized medical fluid injector system, both claims recite steps that are tied to the structure of the injector system, which therefore makes them statutory. The steps of entering a mode and storing a syringe definition are performed on the injector system, and therefore meet the requirements of Bilski cited above in that the method is tied to a particular apparatus.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 21-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Canadian Patent No. 1,329,946 to Koenig (Koenig) in view of U.S. No. 6,200,289 to Hochman (Hochman).

In Reference to Claims 21-24

Koenig teaches a method of operation of an injector system comprising: entering a mode (instrument configuration mode) that permits use of service related functions by a service technician different from those involved in medical injection (p. 8, lines 11-17; p. 12, lines 8-10; p. 24, lines 8-27); changing the default settings of the injector (p. 26, lines 2-15); and storing these new settings in the injector (p. 26, lines 7-9, wherein the input settings replace, and therefore update, the default settings and are therefore stored in the system). Koenig further teaches wherein this injection pump can be a syringe pump (p. 4, lines 19-26). Koenig fails to explicitly teach receiving one or more syringe constants and then calculating an additional syringe constant based on the inputted constant. Hochman teaches an injector pump that comprises a memory 160 that stores data banks related to syringes (col. 8, lines 38-42). In storing the syringe characteristics in the data bank of Hochman, a user would have entered the values for syringe length, stroke length, and volume and then stored it as a particular definition capable of being accessed during the operational mode (col. 9, lines 23-41). Further, if syringe stroke length and volume are known, then the user would be capable of calculating an additional syringe constant (e.g. cross-sectional area by dividing volume by the stroke of the syringe, col. 9, lines 50-53). This data bank stores information on different syringes in order to enable the user during the operational mode to select a syringe and receive its physical characteristics from the stored database without having to manually enter all of the syringe characteristics during operation setup (col. 9, lines 25-41).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Koenig to have the physical characteristics of a syringe (e.g. length, volume, stroke length) which can be stored in a memory data bank as taught by Hochman be the settings that the operator adjusts in the instrument configuration mode in order to enable the user during the operational mode to select a syringe and receive its physical characteristics from the stored database without having to manually enter all of the syringe characteristics during operation setup (col. 9, lines 25-41).

In Reference to Claims 25 and 26

Koenig in view of Hochman teaches the method of claim 21 (see rejection of claim 21 above). Koenig further teaches exiting the service mode and entering an operational mode for use in medical procedures, wherein the operational routine relies on the syringe definition (p. 24, lines 8-18, wherein during the service mode the instrument is not in normal operation and infusing fluid, and therefore the service mode must be exited prior to pump operation).

In Reference to Claim 27-29

Koenig teaches a method of operation of an injector system comprising: entering a mode (instrument configuration mode) that permits use of service related functions by a service technician different from those involved in medical injection (p. 8, lines 11-17; p. 12, lines 8-10; p. 24, lines 8-27); changing the default settings of the injector (p. 26,

lines 2-15); and storing these new settings in the injector (p. 26, lines 7-9, wherein the input settings replace, and therefore update, the default settings and are therefore stored in the system). Koenig further teaches wherein this injection pump can be a syringe pump (p. 4, lines 19-26). Koenig fails to explicitly teach receiving three syringe constants. Hochman teaches an injector pump that comprises a memory 160 that stores data banks related to syringes (col. 8, lines 38-42). In storing the syringe characteristics in the data bank of Hochman, a user would have entered the values for syringe length, stroke length, and volume and then stored it as a particular definition capable of being accessed during the operational mode (col. 9, lines 23-41). Further, if syringe stroke length and volume are known, then the user would be capable of calculating an additional syringe constant (e.g. cross-sectional area by dividing volume by the stroke of the syringe, col. 9, lines 50-53, and then calculating syringe diameter by using the formula for the cross-sectional area of a cylinder. From these calculations, the user would then be capable of having syringe diameter be one constant that is input and stored in the system in addition to the volume and stroke length). This data bank stores information on different syringes in order to enable the user during the operational mode to select a syringe and receive its physical characteristics from the stored database without having to manually enter all of the syringe characteristics during operation setup (col. 9, lines 25-41).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Koenig to have the physical characteristics of a syringe (e.g. length, volume, stroke length, and diameter) which can

be stored in a memory data bank as taught by Hochman be the settings that the operator adjusts in the instrument configuration mode in order to enable the user during the operational mode to select a syringe and receive its physical characteristics from the stored database without having to manually enter all of the syringe characteristics during operation setup (col. 9, lines 25-41).

In Reference to Claims 30-31

Koenig in view of Hochman teaches the method of claim 27 (see rejection of claim 27 above). Koenig further teaches exiting the service mode and entering an operational mode for use in medical procedures, wherein the operational routine relies on the syringe definition (p. 24, lines 8-18, wherein during the service mode the instrument is not in normal operation and infusing fluid, and therefore the service mode must be exited prior to pump operation).

In Reference to Claims 32, 35, 36, 39, and 40

Koenig teaches a method of operation of an injector system comprising: providing a data collection routine that prompts a user to input information into the injector a mode to change the default settings of the injector, such as infusion rate (p. 26, lines 2-15); and storing these new settings in the injector (p. 26, lines 7-9, wherein the input settings replace and create a new setting, and therefore update, the default settings and are therefore stored in the system). Koenig further teaches wherein this injection pump can be a syringe pump (p. 4, lines 19-26). Koenig fails to explicitly teach

receiving two syringe constants and calculating a third constant based on the input. Hochman teaches an injector pump that comprises a memory 160 that stores data banks related to syringes (col. 8, lines 38-42). In storing the syringe characteristics in the data bank of Hochman, a user would have entered the values for syringe length, stroke length, and volume and then stored it as a particular definition capable of being accessed during the operational mode (col. 9, lines 23-41). Further, if syringe stroke length and volume are known, then the user would be capable of calculating an additional syringe constant (e.g. cross-sectional area by dividing volume by the stroke of the syringe, col. 9, lines 50-53, and then calculating syringe diameter by using the formula for the cross-sectional area of a cylinder. From these calculations, the user would then be capable of having syringe diameter be one constant that is input and stored in the system in addition to the volume and stroke length). This data bank stores information on different syringes in order to enable the user during the operational mode to select a syringe and receive its physical characteristics from the stored database without having to manually enter all of the syringe characteristics during operation setup (col. 9, lines 25-41).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Koenig to have the physical characteristics of a syringe (e.g. length, volume, stroke length, and diameter) which can be stored in a memory data bank as taught by Hochman be the settings that the operator adjusts in the instrument configuration mode in order to enable the user during the operational mode to select a syringe and receive its physical characteristics from the

stored database without having to manually enter all of the syringe characteristics during operation setup (col. 9, lines 25-41).

In Reference to Claims 33 and 34

Koenig in view of Hochman teaches the method of claim 32 (see rejection of claim 32 above). Koenig further teaches wherein one of the default settings is deleted during the process of inputting new settings and the new setting is stored in the memory of the system (p. 26, lines 7-9).

In Reference to Claims 37 and 38

Koenig in view of Hochman teaches the method of claim 32 (see rejection of claim 32 above). Koenig further teaches modifying one or more medical functions and parameters used in the injector that are affected by the updating (p. 15, line 10- p. 22, line 19, wherein the operational routine relies on the syringe definition as for example, during operation the minimum infusion rate that can be set is that set during service mode and stored in the system (p. 19, lines 17-18). Therefore, updating the syringe definition would result in changed settings for the injector system that would affect the calibration and use of the system).

Response to Arguments

7. Applicant's arguments with respect to claims 21-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA E. DOUKAS whose telephone number is (571)270-5901. The examiner can normally be reached on Monday - Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MD

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767